PATENT
ATTORNEY DOCKET NO.: 051438-5002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Nadine BURTON et al.	)	
	)	Confirmation No.: 8062
	)	
Application No.: 10/712,265	)	Group Art Unit: 3761
	)	
Filed: November 14, 2003	)	Examiner: Laura C. Hill
	)	

For: MEDICAL VACUUM ASPIRATION DEVICE

Commissioner for Patents
Mail Stop – Appeal Brief Patents
Alexandria, VA 22314

Sir:

TRANSMITTAL FORM

1. Transmitted herewith is an Appeal Brief dated September 21, 2006.

- ☐ Terminal Disclaimer
- ☐ Drawings: ☐ Formal ☐ Informal (Correction)
- ☐ Information Disclosure Statement
- ☐ Form PTO-1449, _____ references included
- ☐ Citations
- ☐ Substitute Specification

5. Fee Calculation (37 C.F.R. §1.16)

CLAIMS AS AMENDED						
	Claims Remaining After Amendment		Highest No. Previously Paid	Present Extra	at Rate of	Total Fees
Total Claims (37 C.F.R. §1.16(c))	28	minus	28	0	x $50 each=	+ $0
Independent Claims (37 C.F.R.§1.16(b))	3	minus	3	0	x $200 each=	+ $0
[ ] First presentation of Multiple dependent claim(s)					$360.00	+ $
SUB-TOTAL =						$0
Reduction by ½ for filing by a small entity						- $
TOTAL FEE =						$0

6. Fee Payment

☐ No fee is to be paid at this time.

☒ The Commissioner is hereby authorized to charge **$500.00** for Appeal Brief fee to Deposit Account 50-0310 for the extra independent claim fee.

3. Extension of Time

The proceedings herein are for a patent application and the provisions of 37 C.F.R. § 1.136(a) apply.

☒ Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

☐ Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(a), for the total number of months checked below:

Total Months Requested	Fee for Extension	[Fee for Small Entity]
☐ one month	$ 120.00	$ 60.00
☐ two months	$ 450.00	$ 225.00
☐ three months	$ 1,020.00	$ 510.00
☐ four months	$ 1,590.00	$ 795.00

Extension of time fee due with this request: $

If an additional extension of time is required, please consider this a Petition therefor.

☐ An extension for _____months has already been secured and the fee paid therefor of $_____ is deducted from the total fee due for the total months of extension now requested.

4. Constructive Petition

☒ EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).

☒ The Commissioner is hereby authorized to charge any additional fees which may be required, including fees due under 37 C.F.R. §§ 1.16 and 1.17, or credit any overpayment to Deposit Account 50-0310.

Respectfully submitted,

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By: _____
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Dated: September 21, 2006

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PATENT
Attorney Docket No.: 051438-5002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Nadine F. BURTON et al.	)	Confirmation No.: 8062
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Application No.: 10/712,265	)	Group Art Unit: 3761
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For: MEDICAL VACUUM ASPIRATION DEVICE	)	**Mail Stop Appeal Brief Patents**

Commissioner for Patents
Mail Stop Appeal Brief Patents
Alexandria, VA 22314

Sir:

APPELLANT'S BRIEF UNDER 37 C.F.R. § 41.37

This brief is in furtherance of the Notice of Appeal filed in the above-identified patent application on September 20, 2006. A fee of $500.00 required under 37 C.F.R. §41.20(b)(2) is being filed concurrently herewith.

09/22/2006 SDENBOB1 00000078 500310 10712265
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1. The Real Party in Interest

The real party in interest in this appeal is Ipas of Chapel Hill, North Carolina.

2. Related Appeals and Interferences

Appellants are not aware of any other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

3. Status of Claims

The status of the claims is as follows upon filing of this Appeal Brief:

Claims canceled: None.
Claims withdrawn from consideration but not canceled: None
Claims pending: 1-28.
Claims objected to: None
Claims allowed: None
Claims rejected: 1-28.

The claims on appeal are 1-28.

4. The Status of Amendments

Appellants have filed an Amendment under 37 C.F.R. § 1.116 prior filed on September 20, 2006, merely to correct an informality in Claim 28, thereby simplifying issues for appeal and placing the application in better form for appeal. As such, Appellants submit this brief in the understanding that the claim amendment will be entered. Moreover, the Claims provided in the claims appendix herein include the claim amendments of the Amendment under 37 C.F.R. § 1.116.

5. **Summary of Claimed Subject Matter**

The present invention relates to a medical vacuum aspiration device (MVA) that is economical, safe, effective, and easily cleaned and sterilized. Multiple-use MVAs are more economical than single-use MVAs. However, to be used multiple times without risk of infection or spread of disease, the MVA must be sterilized and/or disinfected between uses. MVAs can be difficult to clean and sterilize adequately by virtue of their design. For example, MVAs can have several interfaces between connecting parts for maintaining a vacuum seal in the fluid path extending through the MVA. These interfaces can harbor tissue and fluid that can be difficult to remove during the sterilizing and disinfecting procedures.

An exemplary embodiment of the claimed MVA is shown in Fig. 1 of the present specification (reproduced below).

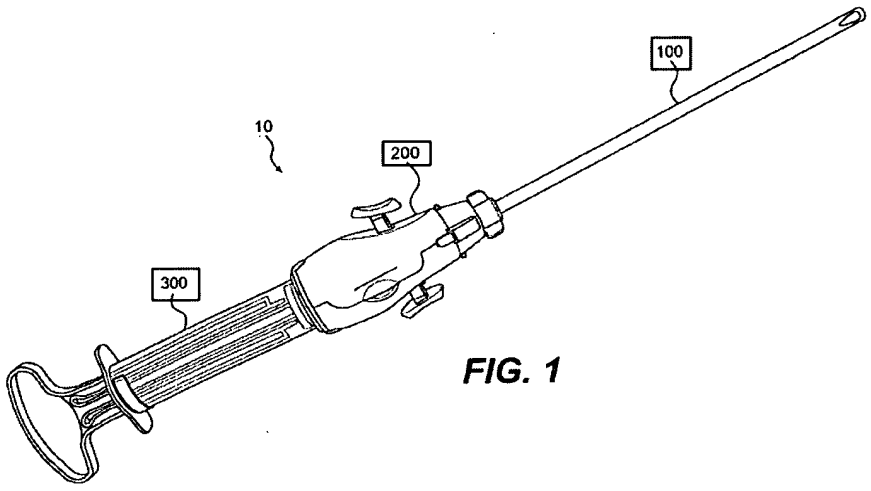

FIG. 1

As shown in the exemplary embodiment shown in Figures 1, 2, 3, and 7, the MVA device of Claim 1 comprises an aspiration cylinder (300) and a valve (200). The valve (200) includes a removable fluid conduit (208, *see* Figs. 3 and 7 reproduced below) having a first end for attaching to the aspiration cylinder (300) and a second end for attaching to a cannula (100); a

valve housing (202, Fig. 3) having at least first and second housing portions (214, 214', Fig. 3) that define a cavity for removably holding at least a portion of the fluid conduit (208); means (a releasable connector, such as hinge straps 222, 224 and latch 226; *see also*, para. 0032, and equivalents) for removably attaching the first housing portion (214) to the second housing portion (214'); and an actuator (button 206), coupled to the valve housing (202), that selectively compresses a portion of the fluid conduit (208) to open and close a suction path defined by the fluid conduit.

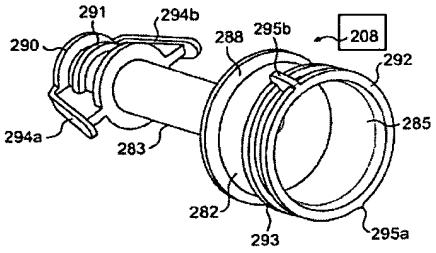

FIG. 7

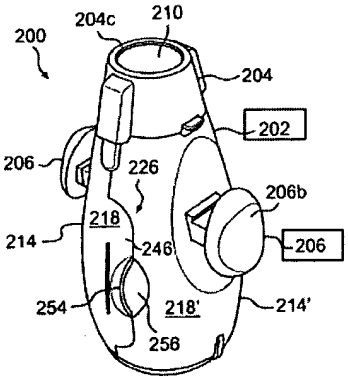

FIG. 2

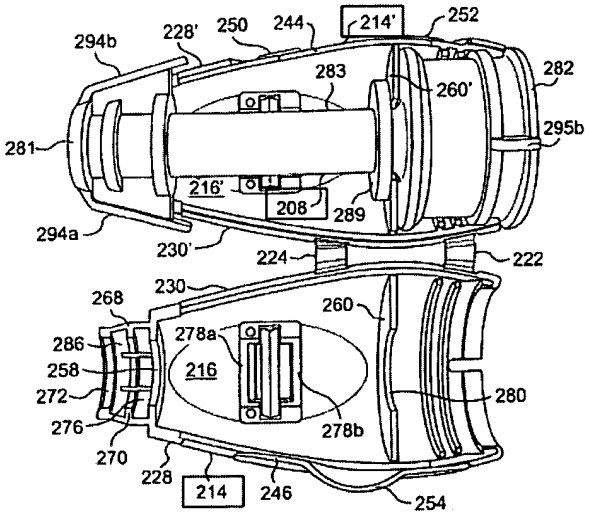

FIG. 3

Independent Claim 15 is also directed to an MVA device. As illustrated in the exemplary embodiments of Figs. 1, 2, 3, and 7, the MVA device includes an aspiration cylinder (300) and a valve (200) adapted for fluid communication with the aspiration cylinder (300). The valve (200) includes first and second housing portions (214, 214'), each including inner and outer walls; a releasable connector (226) joining the first housing portion (214) to the second housing portion (214') such that the first housing portion and the second housing cooperate to define a housing (202) having first and second open ends and a cavity defined by the inner walls and extending between the first and second open ends; a fluid conduit (208); and at least one conduit clamp (206e).

The fluid conduit (208) is retained in the cavity when the first and second housing portions (214, 214') are joined by the releasable connector (226) and is exposed for removal from the cavity when the releasable connector is released. The fluid conduit (208) includes a flexible conduit portion. The at least one conduit clamp (206e) is movably mounted on one of the housing portions (214, 214') and is engagable with the flexible conduit portion to compress the conduit portion (208).

Independent claim 28 is directed to an MVA device comprising an aspiration syringe (300); a cannula (100); and a valve (200) for controlling suction generated by the aspiration syringe through the cannula. The valve (200) comprises a valve housing (202) having a cavity; tubing (208) removably seated within the cavity and coupled in between the aspiration syringe (300) and the cannula (100); and an actuator (206) that selectively compresses a portion of the tubing (208) to open and close a suction path between the aspiration syringe (300) and the cannula (100).

While Independent Claims 1, 15, and 28 have antecedent in the present specification and drawings, it should be understood that the invention is not intended to be limited to the exemplary embodiments of the specification and drawings.

6. Grounds of Rejection to be Reviewed on Appeal

Claims 1-3, 5-7, 10-11, 13-24, and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,909,792 to *Norelli* in view of U.S. Patent No. 5,591,134 to *Shu* and further in view of U.S. Patent No. 5,749,859 to *Powell*.

Claims 4 and 25-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,909,792 to *Norelli* in view of U.S. Patent No. 5,591,134 to *Shu* and further in view of U.S. Patent No. 5,749,859 to *Powell*, as applied to Claim 1, and further in view of U.S. Patent No. 6,632,201 to *Mathias*.

Claims 9 and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,909,792 to *Norelli* in view of U.S. Patent No. 5,591,134 to *Shu* and further in view of U.S. Patent No. 5,749,859 to *Powell*, as applied to Claim 1, and further in view of U.S. Patent No. 5,102,394 to *Lasaitis et al.*

7. Argument

Appellants respectfully assert that the rejections under 35 U.S.C. §§ 103 are improper and should be reversed because (1) the applied art does not teach or suggest each of the features of independent claims 1, 15, and 28, and (2) it would not have been obvious to one skilled in the art

to combine the references as proposed by the Examiner to produce the invention recited in independent Claims 1, 15, and 28.

A. Independent Claim 1

The Examiner rejects Independent Claim 1 under 35 U.S.C. § 103(a) as being unpatentable over *Norelli* in view of *Shu*, and further in view of *Powell*. The primary reference relied upon, *Norelli*, relates to a safety cover for a syringe needle that protects against needle sticks.

The Office Action concedes the *Norelli* does not disclose "means for removably attaching the first housing portion to the second housing portion" or "an actuator for opening and closing a suction path defined by the fluid conduit" as recited in Independent Claim 1. However, *Norelli* and the other references relied upon also lack other features of Independent Claim 1. None of references relied upon disclose a valve having (1) "a removable fluid conduit having a first end for attaching to the aspiration cylinder and a second end for attaching to a cannula" where "an actuator ... selectively compresses a portion of the fluid conduit to open and close a suction path defined by the fluid conduit"; (2) a valve housing having at least first and second housing portions that define a cavity for removably holding at least a portion of the fluid conduit; or (3) "means for removably attaching the first housing portion to the second housing portion", as recited in Independent Claim 1.

As noted above, *Norelli* relates to a safety cover for syringe needles. Fig. 6 of *Norelli*, which is cited by the Examiner, is reproduced below.

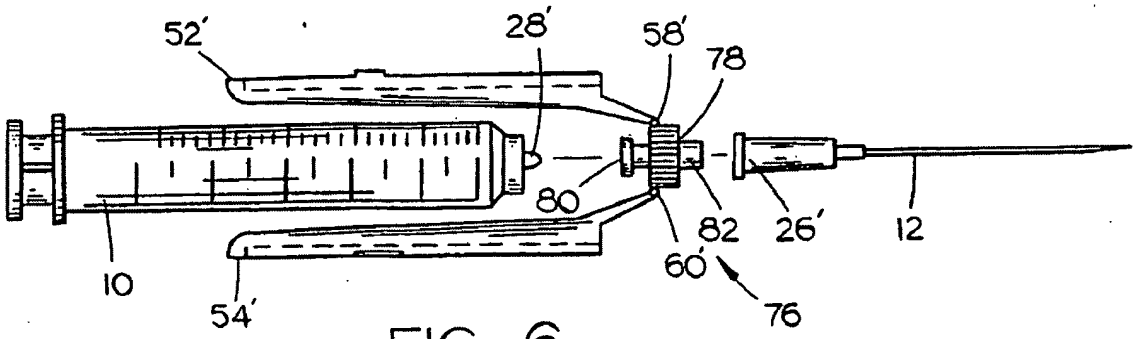

FIG. 6

Norelli discloses a safety cover 76 that connects a syringe 10 and a needle 12. The safety cover includes jaws 52', 54' connected, respectively, via hinges 58', 60' to an adapter 78. The jaws 52', 54' pivot toward the needle 12 to cover the needle 12 to prevent accidental needle sticks.

In addition to the "means for removably attaching" and the "actuator" of Claim 1, which the Examiner concedes are lacking, *Norelli* fails to disclose the valve arrangement recited in Independent Claim 1. The Examiner equates the syringe 10 of *Norelli* to the valve's "removable fluid conduit having a first end for attaching to the aspiration cylinder and a second end for attaching to a cannula" recited in Claim 1. Appellants disagree with this characterization. The syringe 10 of *Norelli* is not part of a "valve" as recited in Claim 1. Moreover, equating the syringe 10 of *Norelli* to the "removable fluid conduit" of Claim 1 would mean that *Norelli* fails to include the "aspiration cylinder" of Claim 1.[1] Furthermore, Independent Claim 1 recites that the actuator "selectively compresses a portion of the fluid conduit to open and close a suction path defined by the fluid conduit." Neither the syringe 10 nor the safety device 50 in *Norelli* is

compressed or designed to be compressed. Therefore, neither the syringe 10 nor the safety device 50 can be the "removable fluid conduit" of Independent Claim 1.

Further, contrary to the Examiner's allegation, the safety device 50 (Fig. 3) is not a "valve housing having at least first and second housing portions that define a cavity for removable holding at least a portion of the fluid conduit," as the Examiner alleges. The safety device 50 in *Norelli* covers the needle 12 to prevent accidental needle sticks. *Norelli* does not disclose a valve and, thus, does not disclose a valve housing.

The Examiner's secondary reference, *Shu*, is also directed to a protective needle cover. Fig. 7 of *Shu* is reproduced to the right. The *Shu* needle cover has a cylindrical body 1 divided into two halves 12, 13. A retaining hole 15 and projected hook 16 are provided to detachably connect the two halves. The bottom rim 17 is dimensioned to engage with the projected seat 22 of the syringe 2 when the halves 12, 13 are connected, thereby fastening the needle cover to the syringe. As shown in Fig. 7, the top of cylinder 1 is closed.

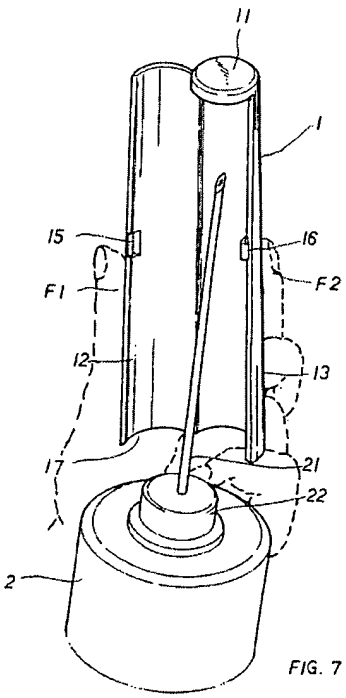

FIG. 7

Shu fails to make up for the above-mentioned deficiencies of *Norelli*. For example, *Shu* does not disclose a valve, a valve housing, a removable fluid conduit, or an actuator, as recited in Claim 1.

The third reference relied on by the Examiner is *Powell*, which is directed to a catheter or cannula system. Fig. 3 of *Powell* is reproduced below.

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[1] The Office Action refers to Fig. 3 and Fig. 6 of *Norelli* interchangeably, notwithstanding that these Figs.

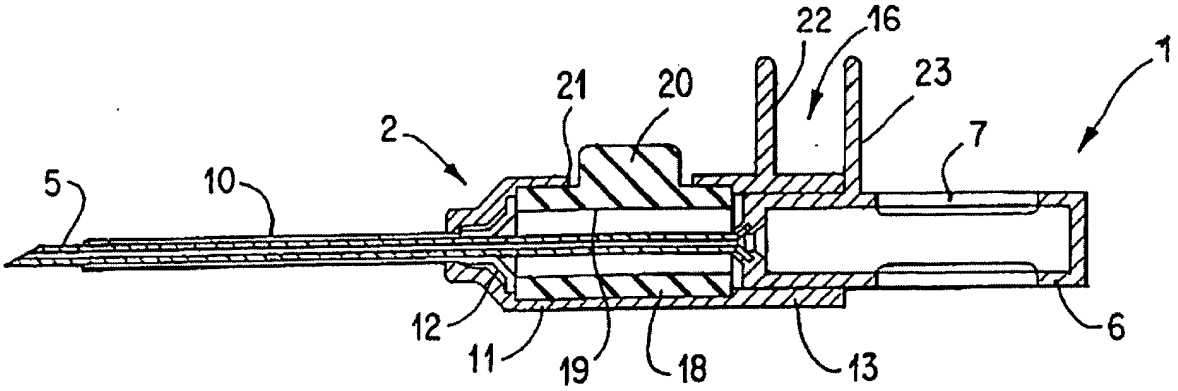

FIG. 3

Powell discloses a trocar 1 having a needle 5 that is inserted into a cannula 2. The cannula 2 includes a cannula tube 10 fitted into a boss 11 on the cannula body 13 by means of a clamping ring 12. The cannula body 13 includes a resilient tube 18 with a button integrally molded into it. In use, the trocar 1 and cannula 2 are joined together, the needle 5 is inserted in the patient and, by observation through a window 7 of the trocar 1, the user can determine whether blood entering the trocar is from a vein. Next, the trocar 1 is withdrawn from the patient while the user depresses button 20. When the trocar 1 is removed, pressure on the button 20 closes off the blood flow path through the cannula 2. This prevents blood from flowing out of the end of the cannula body 13 from which the trocar 1 was removed. *Powell* discloses several embodiments of this arrangement.[2]

Similar, to *Norelli* and *Shu*, *Powell* also lacks the "removable fluid conduit" of Independent Claim 1. *Powell* does not disclose that the resilient tube 18, 75 is removable from

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illustrate different embodiments.

[2] As above, the Examiner refers to structure shown in the separate embodiments of Figs. 1 and 7 of *Powell*.

the cannula body 13, 72. Rather, as shown in Fig. 3 above, cannula 13 appears to have an annular ledge that would prevent removal of the tube 13. While the trocar needle 5 is removable from the cannula 2, there is no disclosure in *Powell* of selectively compressing a portion of needle 5 to open and close a suction path, as recited in Independent Claim 1. Thus, *Powell* does not disclose the "removable fluid conduit" of Independent Claim 1.

Similarly, *Powell* also fails to disclose "a valve housing having at least first and second housing portions for removably holding at least a portion of the fluid conduit" or "means for removably attaching the first housing portion to the second housing portion." The cannula body 13 disclosed by *Powell* has a monolithic design that prevents a first housing portion from removably attaching to a second housing portion.

Thus, even if combined as alleged by the Examiner, the combination of *Norelli*, *Shu*, and *Powell* do not disclose each of the features of Independent Claim 1. For this reason, the rejection of Independent Claim 1 based on the combination of *Norelli*, *Shu*, and *Powell* should be reversed.

In addition, there would have been no motivation to combine *Norelli*, *Shu*, and *Powell* as alleged by the Examiner to produce the invention of Claim 1. According to the Examiner, one would be motivated to modify the safety device of *Norelli* with the hinge and latch of *Shu* for "a pivotable valve housing with openable walls since the references are in the same field of endeavor; medical cylinders with removable [sic] and enclosing valve housing." Next, it would have been obvious to modify the combination of *Norelli* and *Shu* "with the actuator [of *Powell*] for controlling the fluid path in the conduit since the references are in the same field of endeavor;

medical cylinders with removable [sic] and enclosing valve housing mechanisms." Appellants respectfully disagree.

Even if the references were in the same field of endeavor, this alone is insufficient to establish that the particular combination would have been obvious. *See, e.g., Manual of Patent Examining Procedure at § 2143 ("there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings.").* The mere fact that the references come from the "same field of endeavor" does not provide a suggestion or motivation to combine the references as proposed.

Moreover, the references are not from the field of "medical cylinders with removable [sic] and enclosing valve housing mechanisms" as the Examiner alleges. *Norelli* and *Shu* are directed needle covers, not valve housings, and *Powell* is directed to a cannula system to be used as a trocar.

In addition, particular combinations of *Norelli*, *Shu*, and *Powell* are problematic. The Examiner proposes modifying the safety device 50 of *Norelli* with the hinge and latch of *Shu* to provide "a pivotable valve housing with openable walls." However, the safety device 50 of *Norelli* is not a valve housing as alleged. There would have been no motivation to modify a valve housing in view of the needle cover disclosed by *Shu*.

The Examiner also proposes to modify the *Norelli/Shu* combination to include "an actuator for controlling the fluid path in the conduit" apparently based on *Powell*. Claim 1 recites "an actuator, coupled to the valve housing, that selectively compresses a portion of the fluid conduit to open and close a suction path defined by the fluid conduit." In *Norelli* and *Shu*,

there is no reason to provide an actuator for selectively compressing the fluid path in the syringe 10. The syringe already has a plunger to control the fluid path. *Powell* provides a button 20 to close the end of the cannula 13 when the trocar 1 is removed. None of the references teach removing the plunger of the syringe 10. There is no reason to provide a button to compress the fluid path in the syringe barrel. Moreover, there is no teaching or suggesting of providing a button coupled to the safety device 50 of *Norelli* (the alleged valve housing), which is modified in view of *Shu*, to compress the syringe barrel. The typical materials used to form syringe barrels are not compressible. It is difficult to imagine how such a structure would be arranged or operated.

The rejection is improper because the Examiner has simply pieced together elements from the needle cover art with elements to a cannula system using Claim 1 as a template. Such modification is the result of impermissible hindsight. In fact, there is no suggestion or motivation to combine *Norelli* with *Shu* and with *Powell* to produce the invention recited in Independent Claim 1.

Because (1) the combination of *Norelli* with *Shu* and with *Powell* does not disclose each of the features of Independent Claim 1, and (2) there would have been no motivation to combine *Norelli* with *Shu* and with *Powell* to produce the invention of Independent Claim 1, the rejection of Independent Claim 1 should be reversed.

B. Independent Claims 15 and 28

The Examiner does not address Independent Claims 15 and 28 with any particularity. With respect to Claim 15, the combination of *Norelli*, *Shu*, and *Powell* fails to disclose "a valve adapted for fluid communication with the aspiration cylinder" where the valve includes (1) "a

releasable connector joining the first housing portion to the second housing portion ..."; and (2) "a fluid conduit retained in the cavity when the first and second housing portions are joined by the releasable connector, and the fluid conduit exposed for removal from the cavity when the releasable connector is released, the fluid conduit including a flexible conduit portion."

As above, neither *Norelli* nor *Shu* disclose a valve. They disclose needle covers for syringes. *Powell* does not disclose a valve having "a releasable connector joining the first housing portion to the second housing portion" or "a fluid conduit retained in the cavity when the first and second housing portions are joined by the releasable connector, and the fluid conduit exposed for removal from the cavity when the releasable connector is released, the fluid conduit including a flexible conduit portion." As above, the cannula body 13 disclosed in *Powell* has a monolithic design and thus does not provide "a releasable connector joining the first housing portion to the second housing portion." Likewise, the "fluid conduit" recitation in Claim 15 is not met by *Powell*. Thus, the combination of *Norelli*, *Shu*, and *Powell* do not disclose each of the features of Independent Claim 15.

The Examiner uses the same rationale for combining *Norelli*, *Shu*, and *Powell* to reject Claim 15 as used in rejecting Claim 1. The rationale is improper as discussed above in connection with Claim 1. There is no motivation or suggestion for combining *Norelli*, *Shu*, and *Powell* as proposed by the Examiner. Accordingly, the rejection of Claim 15 should be reversed.

With respect to Claim 28, the combination of *Norelli*, *Shu*, and *Powell* fails to disclose (1) "a valve for controlling suction generated by the aspiration syringe through the cannula"; (2) "tubing removably seated within the cavity [of the valve housing], the tubing coupled in between the aspiration syringe and the cannula"; and (3) "an actuator that selectively compresses a

portion of the tubing to open and close a suction path between the aspiration syringe and the cannula."

Norelli and *Shu* disclose needle covers. They do not disclose "a valve for controlling suction generated by the aspiration syringe through the cannula." *Powell* does not disclose "a valve for controlling suction generated by the aspiration syringe through the cannula" because *Powell* does not disclose an aspiration syringe.

The needle cover designs of *Norelli* and *Shu* do not include the "tubing removably seated within the cavity, the tubing coupled between the aspiration syringe and the cannula" as recited in Independent Claim 28. *Norelli* discloses a syringe with a safety cover. The alleged tubing in *Norelli* (i.e., the syringe 10) is not part of a valve, is not seated within a cavity of a valve housing, and is not coupled between an aspiration syringe and a cannula. Similarly, the needle cover in *Shu* is positioned over the needle. It is neither "removably seated within the cavity" nor "coupled between the aspiration syringe and the cannula." Likewise, *Powell* does not disclose "tubing removably seated within the cavity [of the valve housing], the tubing coupled in between the aspiration syringe and the cannula." *Powell* does not disclose that resilient tube 18, 75 is removable, nor is there any disclosure of the aspiration syringe.

The Examiner admits that *Norelli* and *Shu* do not disclose an "actuator" as recited in Claim 28. Because *Powell* lacks an aspiration syringe, it does not disclose "an actuator that selectively compresses a portion of the tubing to open and close a suction path between the aspiration syringe and the cannula."

The Examiner's rationale for combining *Norelli*, *Shu*, and *Powell* to reject Independent Claim 28 is the same as used in rejecting Claim 1. As discussed above in connection with Claim

1, there is no motivation or suggestion for combining *Norelli*, *Shu*, and *Powell* as proposed by the Examiner. Accordingly, the rejection of Claim 28 should be reversed.

C. Dependent Claims

Appellants respectfully assert that Dependent Claims 2-14 and 16-27 are allowable at least because of their respective dependencies from Independent Claims 1 and 15, and the reasons set forth above. Thus, the rejection of Dependent Claims 2-14 and 16-27 are improper and should be reversed.

1. Dependent Claim 2

In addition, the rejection of Claim 2 is improper. The Examiner apparently relies upon the *Norelli* embodiment shown in Fig. 3 to reject Claim 2. The Examiner states that in *Norelli* the jaws 52, 54 are connected to the syringe barrel 56 by hinges 58, 60 to form a "single-piece unit." The Office Action cites to column 4, lines 60-65 of *Norelli*, which refer to the embodiment of Fig. 3. The Examiner thus equates the jaws 52, 54 in *Norelli* with "the valve housing having first and second housing portions ...."

Claim 2 depends from Claim 1. Claim 1 recites "a valve housing having at least first and second housing portions that define a cavity for removably holding at least a portion of the fluid conduit." The Examiner alleges that the "fluid conduit" is met by the syringe 10. *Norelli* fails to disclose "a valve housing ... for removably holding at least a part of the fluid conduit" because the jaws 52, 54 (the alleged housing portions) shown in Fig. 3 are connected to the syringe barrel 56. Therefore, the jaws 52, 54 do not removably hold at least part of the fluid conduit.

2. Dependent Claims 4, 25 and 26

Claims 4, 25 and 26 are rejected based on *Norelli* in view of *Shu*, further in view of *Powell*, and further in view of *Mathias*. *Mathias* relates to a needle protector for a blood collection device. The needle protector 40 includes a housing 42 that provides a compartment for receiving a needle 12. The needle protector can be slid over the needle 12 to prevent accidental needle sticks. The Examiner relies on *Mathias* to disclose a sterilizable propylene material for the needle protector housing 42. *Mathias* does not make up for the deficiencies of *Norelli*, *Shu*, and *Powell*. The rejection of these claims should be reversed for at least the reasons provided above.

3. Dependent Claims 5 and 6

With respect to Claims 5 and 6, the Examiner shifts again to Fig. 6 of *Norelli*, which depicts a different embodiment than in Fig. 3. The Examiner alleges that female connected socket 80 (which the Examiner has re-named "a first receptacle') is proximate the first end of syringe 10 (which the Examiner as re-named as "fluid conduit") for receiving an end of the aspiration cylinder. The Examiner also asserts that the socket 80 and the syringe 10 comprise "an integrally formed conduit component such that the path extends continuously through the conduit." First, it is plain to see in Fig. 6 of *Norelli* that the socket and syringe 10 are separate pieces and thus are not "integrally formed" as recited in Claim 6. Second, Claim 5 requires that the "fluid conduit" comprise a "first receptacle for receiving an end of the aspiration cylinder." The Examiner alleges that the syringe 10 in *Norelli* is the claimed "fluid conduit." Consequently, the socket 80 receives an end of the syringe 10, which cannot be both the claimed "fluid conduit" and the "aspiration syringe." Thus, the combination of *Norelli*, *Shu*, and *Powell*

fail to teach or suggest the features of Claims 5 and 6. The rejection of these claims should be reversed.

4. Dependent Claims 7-8 and 27

With respect to Claims 7-8 and 27, the Office Action states that *Norelli* discloses the conduit (i.e., the syringe 10) may be made of a flexible or elastomeric or plastics material such as silicon rubber, citing to Column 2, lines 31-34. *Norelli* contains no such disclosure. *Powell* discloses that the tube 18 may be made from a flexible or elastomeric or plastics material such as silicon rubber. There is no teaching or suggestion to use such a material for the syringe 10 and socket 80 of *Norelli*, which the Examiner alleges form the claimed "fluid conduit." Further, there is no reasonable expectation that forming a syringe of a flexible material would be successful. *See MPEP 2143*. The rejection of Claims 7-8 and 27 should be reversed.

5. Dependent Claims 9 and 12

Claims 9 and 12 are rejected based on *Norelli* in view of *Shu*, further in view of *Powell*, and further in view of *Lasaitis*. *Lasaitis* relates to a catheter assembly with a catheter member 12, needle member 20 telescopically positioned within the catheter member 12, and a protective shield member 34. The needle member 20 includes a tab or fin projection 30 to facilitate manipulation of the needle member 20. A protective shield member 34 has a tubular shape with an open end that can be positioned over the catheter member 12 as shown in Fig. 2 of *Lasaitis* to enclose the tube part of the catheter member 12. Alternatively, the catheter member 12 can be positioned so that the tube extends from the open end of the protective shield member 34. The needle member 22 can be withdrawn from the catheter member into the protective shield 34, as shown in Fig. 4 of *Lasaitis*.

Lasaitis does not make up for the deficiencies of *Norelli*, *Shu*, and *Powell*. The rejection of Claims 9 and 12 should be reversed for at least the reasons provided above. Moreover, *Lasaitis* does not disclose a valve housing as alleged by the Examiner. The protective shield member 34 is not a valve housing.

6. Dependent Claims 10 and 11

Claims 10 and 11 are rejected based on the combination of *Norelli*, *Shu*, and *Powell*. However, these claims depend from Claim 1 through Claim 9. The Examiner concedes that *Norelli*, *Shu*, and *Powell* fail to disclose the features of Claim 9. Therefore, the rejection of Claims 10 and 11, which incorporate Claim 9, is improper and should be reversed.

7. Dependent Claims 13 and 14

With respect to Claims 13 and 14, the Examiner alleges that gasket 134 of *Norelli* provides the claimed "sealing receptacle." This is not the case. Claim 13 recites that the "fluid conduit further comprises a sealing receptacle adapted to cooperate with the aspiration cylinder to provide a fluid seal between the aspiration cylinder and the fluid conduit." Claim 14 provides that "the sealing receptacle is integrally formed portion of the fluid conduit." The gasket 134 of *Norelli* is seated in the jaws of the needle cover. *See Figs. 10 and 11 of Norelli.* The gasket is not an integrally formed portion of the fluid conduit (which the Examiner alleges to be the syringe 10) and does not provide a fluid seal between the aspiration syringe and the fluid conduit.

# # # # #

In view of the foregoing, Appellant respectfully requests the reversal of the Examiner's rejections and the allowance of the pending claims. If there are any other fees due in connection

with the filing of this Appellant's Brief, please charge the fees to our Deposit Account No. 50-0310.

If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account No. 50-0310.

Respectfully submitted,
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Dated: September 21, 2006

By: _____
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8. Claims Appendix

Subsequent to entry of the Amendment under 37 C.F.R. § 1.116, the claims read as follows:

Claim 1 (Previously Presented): A medical vacuum aspiration device comprising:

an aspiration cylinder; and

a valve, the valve comprising:

a removable fluid conduit having a first end for attaching to the aspiration cylinder and a second end for attaching to a cannula;

a valve housing having at least first and second housing portions that define a cavity for removably holding at least a portion of the fluid conduit;

means for removably attaching the first housing portion to the second housing portion; and

an actuator, coupled to the valve housing, that selectively compresses a portion of the fluid conduit to open and close a suction path defined by the fluid conduit.

Claim 2 (Original): The medical vacuum aspiration device according to claim 1, wherein the first and second housing portions and the means for removably attaching comprise a single-piece unit.

Claim 3 (Original): The medical vacuum aspiration device according to claim 2, wherein the single-piece unit comprises plastic.

Claim 4 (Original): The medical vacuum aspiration device according to claim 3, wherein the plastic comprises polypropylene.

Claim 5 (Original): The medical vacuum aspiration device according to claim 1, wherein the fluid conduit further comprises a first receptacle proximate the first end, the first receptacle for receiving an end of the aspiration cylinder to provide a sealed connection between the fluid conduit and the aspiration cylinder.

Claim 6 (Previously Presented): The medical vacuum aspiration device according to claim 5, wherein the fluid conduit and the first receptacle comprises an integrally formed conduit component such that the path extends continuously through the fluid conduit.

Claim 7 (Original): The medical vacuum aspiration device according to claim 6, wherein the integrally formed conduit component comprises a resilient material.

Claim 8 (Original): The medical vacuum aspiration device according to claim 7, wherein the resilient material comprises silicone.

Claim 9 (Original): The medical vacuum aspiration device according to claim 1, wherein the first and second housing portions engage the fluid conduit to restrain movement of the fluid conduit relative to the housing.

Claim 10 (Original): The medical vacuum aspiration device according to claim 9, the valve further comprising a cap that connects to the first and second housing portions.

Claim 11 (Original): The medical vacuum aspiration device according to claim 10, wherein a portion of the fluid conduit extends outwardly from an end of the housing and the cap extends over the portion of the fluid conduit.

Claim 12 (Original): The medical vacuum aspiration device according to claim 11, wherein the cap engages the fluid conduit to restrain movement of the fluid conduit relative to the housing.

Claim 13 (Original): The medical vacuum aspiration device according to claim 1, wherein the fluid conduit further comprises a sealing receptacle adapted to cooperate with the aspiration cylinder to provide a fluid seal between the aspiration cylinder and the fluid conduit.

Claim 14 (Original): The medical vacuum aspiration device according to claim 13, wherein the sealing receptacle is integrally formed portion of the fluid conduit.

Claim 15 (Original): A medical vacuum aspiration device comprising:

an aspiration cylinder; and

a valve adapted for fluid communication with the aspiration cylinder, the valve including:

first and second housing portions, each including inner and outer walls;

a releasable connector joining the first housing portion to the second housing portion such that the first housing portion and the second housing cooperate to define a housing having first and second open ends and a cavity defined by the inner walls and extending between the first and second open ends;

a fluid conduit retained in the cavity when the first and second housing portions are joined by the releasable connector, and the fluid conduit exposed for removal from the cavity when the releasable connector is released, the fluid conduit including a flexible conduit portion; and

at least one conduit clamp movably mounted on one of the housing portions and engagable with the flexible conduit portion to compress the conduit portion.

Claim 16 (Original): The medical vacuum aspiration device according to claim 15, further comprising a hinge about which the first housing portion pivots relative to the second housing portion.

Claim 17 (Original): The medical vacuum aspiration device according to claim 16, wherein the hinge comprises a living hinge.

Claim 18 (Original): The medical vacuum aspiration device according to claim 17, wherein the hinge comprises two living hinges integrally formed on the housing portions.

Claim 19 (Original): The medical vacuum aspiration device according to claim 18, wherein each of the living hinges comprises a double living hinge.

Claim 20 (Original): The medical vacuum aspiration device according to claim 16, wherein the releasable connector comprises a releasable latch.

Claim 21 (Original): The medical vacuum aspiration device according to claim 20, wherein the releasable latch comprises a latch tab extending from an edge of one of the housing portions and a tab recess in an outer surface of another one of the housing portions, the tab recess releasably receiving the latch tab when the releasable connector joins the housing portions.

Claim 22 (Original): The medical vacuum aspiration device according to claim 21, wherein the latch tab further comprises a dome portion cooperating with the tab recess to define a user interface space.

Claim 23 (Original): The medical vacuum aspiration device according to claim 22, wherein the latch tab and tab recess are integrally formed on a respective one of the housing portions.

Claim 24 (Original): The medical vacuum aspiration device according to claim 15, wherein the valve further comprising a cap connected to at least one of the first and second ends of the housing.

Claim 25 (Previously Presented): The medical vacuum aspiration device according to claim 1, wherein the valve is a plastic that can be sterilized.

Claim 26 (Previously Presented): The medical vacuum aspiration device according to claim 1, wherein the housing comprises polypropylene.

Claim 27 (Previously Presented): The medical vacuum aspiration device according to claim 1, wherein the fluid conduit comprises silicone.

Claim 28 (Currently Amended): A medical vacuum aspiration device comprising:

an aspiration syringe;

a cannula; and

a valve for controlling suction generated by the aspiration syringe through the cannula, the valve comprising:

a valve housing having a cavity;

tubing removably seated within the cavity, the tubing [between] coupled in between the aspiration syringe and the cannula; and

an actuator that selectively compresses a portion of the tubing to open and close a suction path between the aspiration syringe and the cannula.

9. Evidence Appendix

No information is appended under this section.

10. Related Proceedings Appendix

No information is appended under this section.